Billing Code 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Applying Novel Methods to Better Understand the Relationship between Health IT and Ambulatory Care Workflow Redesign." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by (insert date 60 days after date of publication).

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by email at OIRA_submission@omb.eop.gov (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Applying Novel Methods to Better Understand the Relationship between Health IT and Ambulatory Care Workflow Redesign

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the project "Applying Novel Methods to Better Understand the Relationship between Health IT and Ambulatory Care Workflow Redesign." The data to be collected consists of interviews and focus groups with clinical, non-clinical, and management staff about their experiences with new health information technology (IT) in an ambulatory care facility. The overall goal of this study is to characterize the relationship between health IT implementation and health care workflow in six (6) small and medium-sized ambulatory care practices implementing patient-centered medical homes (PCMH), with a focus on the influence of behavioral and organizational factors and the effects of disruptive events.

AHRQ is a lead Federal agency in developing and disseminating evidence and evidence-based tools on how health IT can improve health care quality, safety, efficiency, and effectiveness. Health IT has been widely viewed as holding great

promise to improve the quality of health care in the U.S. Health IT can improve access to information for both patients and providers, empowering patients to become involved in their own self-care. Increased patient safety can result from health IT when records are shared, medications are reconciled, and adverse event alerts are in place. When health IT improves efficiency, providers can spend more time directly caring for patients, ultimately improving the quality of care patients receive.

In redesigning an ambulatory office practice as a patient-centered medical home (PCMH), health IT is intended to allow for a seamless and organized flow of information among providers. The health IT system is critical, because under the PCMH model, a team of clinicians aims to provide continuous and coordinated care throughout a patient's lifetime.

Unfortunately, health IT systems can fail to generate anticipated results and even carry unintended consequences which undermine usability and usefulness. Directly or indirectly, health IT may create more work, new work, excessive system demands, or inefficient workflow (the sequence of clinical tasks). Electronic reminders and alerts may be timed poorly. Software may require excessive switching between screens, leading to cognitive distractions for end users. Providers may spend more time on health IT system-related tasks than on direct patient care.

The literature also suggests that the ambulatory health care environment is full of unpredictable yet frequently occurring events requiring actions that deviate from normal practice. Unpredictable events such as interruptions requiring a provider's immediate attention, or disruptions in the normal functioning of the health IT system (exceptions) divert health care workers from the usual course

of workflow. The inability of health IT to properly accommodate these events could cause compromises to clinical work.

Because of adverse, unintended and disruptive consequences, developing an understanding of how health IT implementation alters clinical work processes and workflow is crucial. Unfortunately, research is scarce, and methods of investigation vary widely. Empirical evidence of health IT's impact on clinical workflow has been "anecdotal, insufficiently supported, or otherwise deficient in terms of scientific rigor" (Carayon and Karsh, 2010).

This study aims to examine more systematically the impact of health IT on workflow in six (6) small and medium-sized ambulatory care practices varying in their characteristics but all implementing PCMH. All of the practices will be in the process of implementing a new health IT system during the course of the study, but some may have an existing, baseline system such as an electronic health record system. The focus of the study will be on the new systems being implemented. It will employ the complementary quantitative and qualitative methods of previous research. The combination of methods produces quantitative results and allows validation through observation and solicitation of qualitative participant opinions.

The specific goals of this study are to identify 1) the relationship between health IT implementation and ambulatory care workflow; 2) the behavioral and organizational factors and the role they play in mitigating or augmenting the impact of health IT on workflow; and 3) how the impacts of health IT are magnified through disruptive events such as interruptions and exceptions.

This study is being conducted by AHRQ through its contractor, Billings Clinic, pursuant to AHRQ's statutory authority to conduct and support research on

healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to clinical practice, including primary care and practice-oriented research. 42 U.S.C. 299a(a)(1) and (4).

Method of Collection

To achieve the goals of this project the following data collection will be implemented:

1) Mapping of Study Practices. This activity will detect any changes made to the physical layout as a result of implementing PCMH and health IT. Practices will be mapped at the beginning of the study and maps will be updated as needed. Recording this information will not burden the clinic staff and is not included in the burden estimates.

2) Staff Observation. Clinicians (physicians, nurse practitioners, physician assistants, nurses, medical assistants, pharmacists, and case managers) and non-clinical office personnel will be observed to delineate the overall characteristics of clinical workflow before, during, and after health IT implementation. Particular attention will be paid to interruptions and exceptions. If necessary and if the situation allows, observers will as unobtrusively as possible ask clinic staff to clarify certain observed actions. Recording this information will not burden the clinic staff and is not included in the burden estimates.

3) Before--After Time and Motion Study. This activity quantifies staffs time expenditures on different clinical activities and delineates the sequence of task execution. It will be conducted before and after health IT implementation.

This data will be collected by observation only. Recording this information will not burden the clinic staff and is not included in the burden estimates.

4) Extraction of Clinical Data. Logs, audits trails, and time-stamped clinical data will be extracted from the health IT system to reconstruct clinical workflow related to the health IT system. This information validates and supplements the data recorded by human observers. Extracting this data will not burden the clinic staff and is not included in the burden estimates.

5) Semi-Structured Interviews. This data collection will be conducted post-health IT implementation to solicit attitudes and perceptions by health IT end users including clinical staff, non-clinical personnel, and management regarding how health IT has changed their workflow. Particular attention will be paid to behavioral and organizational factors.

6) Focus Group. A focus group will be conducted post-health IT implementation with the clinical staff, non-clinical personnel, and management team to ensure the research findings, as well as the interpretation of the findings, accurately reflect their experiences using health IT.

On-site data collection will be conducted over a 5-day period during each of three phases. Pre-implementation data collection activities will be conducted prior to user training. During-implementation data collection will begin when staff are instructed to start using the health IT system. Post-implementation data collection will be conducted approximately 3 months after implementation at each study practice.

The qualitative study components of this project, namely staff observations, semi-structured interviews, and focus groups, will generate qualitative data in

the form of observation notes and interview transcripts. The time-and-motion study and the electronic clinical data will produce quantitative information in the form of sequences of clinical activities and information about the duration, location, and performer of each action. Mapping will create annotated floor plans delineating the physical layout of each study clinic, which will be incorporated in the collection and analysis of the data of the other study components.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annual burden hours for participation in this study. The semi-structured interview will be completed by 60 respondents across the 6 clinics (10 per practice) and requires one hour. Sixty (60) clinic staff members will be asked to participate in the focus group across all 6 clinics (10 per practice). The focus group requires no more than 45 minutes. The total annual burden is estimated to be 105 hours.

Exhibit 2 shows the estimated annual cost burden associated with the respondents' time to participate in this research. The total annual burden is estimated to be $5,505.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Semi-Structured Interview	60	1	1	60
Focus Group	60	1	45/60	45
Total	120			105

Exhibit 2. Estimated annualized cost burden

Form Name	Number of	Total	Average	Total cost

	respondents	burden hours	hourly wage rate*	burden
Semi-Structured Interview	60	60	$55	$3,300
Focus Group	60	45	$49	$2,205
Total	120	105		$5,505

*Based upon the mean of the average wages, National Compensation Survey. Occupational wages in the United States July 2010, U.S. Department of Labor, Bureau of Labor Statistics, http://www.bls.gov/ncs/ocs/sp/nctb1477.pdf. For the semi-structured interviews, hourly wage is an average including 2 physicians or surgeons ($85.67), 1 registered nurse ($32.42), 2 non-physician providers (measured here as physician assistants, $43.44), and 1 senior administrator (measured here as "Medical and health services managers," $42.28). For focus groups, 3.34 physicians or surgeons ($85.67), 1.66 non-physician providers (measured here as physician assistants, $43.44), 3.34 registered nurses ($32.42), and 1.66 medical assistants ($14.46).

Estimated Annual Costs to the Federal Government

The total cost of this study is $799,014 over a 36-month time period from June 1, 2012 through May 31, 2015 for an annualized cost of $266,338. (Because the project entails gathering data before, during, and after health IT implementation, a period of 21 months is planned for data collection.) Exhibit 3 provides a breakdown of the estimated total and average annual costs by category.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	$135,759	$45,253
Data Collection Activities	$177,460	$59,153
Data Processing and Analysis	$239,426	$79,809
Publication of Results	$51,779	$17,260
Project Management	$67,729	$22,576
Overhead	$126,861	$42,287
Total	$799,014	$266,338

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of

AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: January 16, 2013.

Carolyn M. Clancy, M.D.

Director

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